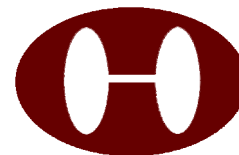


HOG HAPPENINGS



WHY WE MUST FIGHT!

By Quake Pletcher, Hoosier Oncology Group Executive Director



Quake Pletcher, HOG
Executive Director

As I sit on a return flight from Boston to Indy, I feel energized, reflecting upon my seafood dining experience in Logon Airport. It was not the food, but the company that so inspired me.

I had the privilege to dine with a three-time cancer survivor who was heading to the front-lines again – her fourth battle against cancer. I cannot imagine having to fly 4 hours just to participate in a clinical trial in hopes of getting the latest and greatest treatment. But this seasoned warrior does this, knowing it is her best chance of survival.

She was in wonder at the options that HOG presents to patients, and counted as a true blessing that she had the time, financial wherewithal, and several supportive daughters to help her travel so far for her treatments. Not many patients are so blessed.

It is because of chance encounters such as this that I feel proud and humbled by the gift of service the HOG provides...the opportunity for cancer patients to receive cutting-edge cancer therapies in the comfortable surroundings of the home community.

The Hoosier Oncology Group has achieved a milestone that is rare amongst any organization, and rarer still among non-profits. We have reached our Silver Anniversary year. Twenty-five years of advancing the medical field in treating cancer through an incredible partnership between community practices and academic researchers is a very uncommon feat. **Read More...**

LEGISLATION FOR CLINICAL TRIAL PATIENTS

By Susan Haithcox, RN, BSN, CCRP, OCN, Clinical Manager NICRC

In the beginning of 2008, the Northern Indiana Cancer Research Consortium (NICRC), under the direction of principal investigator Dr. Robin Zon, began the lengthy process of working towards legislation for clinical trial participants.

The NICRC is a Community Clinical Oncology Program in the state of Indiana. The NICRC has worked closely with the Hoosier Oncology Group (HOG) since its inception. One of the goals of the HOG and the NICRC are to enroll hematology and oncology patients to state of the art clinical trials while helping participants stay in their own community. In direct relation to this goal, Dr. Zon identified an increasing trend of insurance companies denying coverage for participants trying to enroll onto clinical trials, prompting her to contact the Indiana Cancer Consortium (ICC), confident that the ICC had the capacity and talent to meet this challenge head on.

As a Steering Committee member of the Indiana Cancer Consortium (ICC), I was asked by Dr. Zon to work with the ICC surrounding the issue of insurance coverage for clinical trial participants. Together we worked with the ICC, seeking advice and support from others, including ASCO, with the hope of presenting legislation to the House by the end of session. **Read More...**

If you have an idea for a newsletter feature, please contact Deb Cole at cole22@iupui.edu or call 317.634.5842 x27.

FEATURED RESEARCH

FEATURED RESEARCH: HOG Research Recognized at ASCO

The Hoosier Oncology Group (HOG) holds an impressive record – 4 out of the last 5 years, HOG research outcomes have been featured as an oral presentation at the American Society of Clinical Oncology annual meeting. This year, Dr. Noah Hahn’s investigator-initiated research study, “A Multicenter Phase II Study of Cisplatin (C), Gemcitabine (G), and Bevacizumab (B) As First-Line Chemotherapy for Metastatic Urothelial Carcinoma (UC); Hoosier Oncology Group GU04-75” brought HOG this honor.

“Dr. Hahn's research evaluating the role of bevacizumab in bladder cancer is both unique and important. We are proud of his work and delighted that for the third straight year the Hoosier Oncology Group will be reporting research that will be presented orally at the American Society of Clinical Oncology (ASCO) annual meeting,” said Nasser Hanna, M.D., HOG Chairman and thoracic oncology specialist at the Indiana University Mel and Bren Simon Cancer Center.

“I think overall, the trial was well-received. We knew the findings would generate a healthy discussion due to the fact that we saw an encouraging overall survival in the absence of a significant improvement in progression-free survival with some concerning toxicity” - Noah Hahn, M.D.

Read Article...



Noah Hahn, M.D., GU04-75 Principal Investigator and Genitourinary Oncologist at the Indiana University Simon and Mel Bren Cancer Center

FEATURED RESEARCHER: Mary Jean Wasilewski

Mary Jean Wasilewski joined HOG as an auditor/monitor for physician-initiated studies. She retired one year ago as the Director of the Northern Indiana Cancer Research Consortium CCOP located in South Bend, IN.

Mary Jean’s relationship with HOG started in 1986 as a Research Nurse. During the early years of HOG, Mary Jean served on the HOG Clinical Trials Community Nurse Committee.

The Hoosier Oncology Group is fortunate to have Mary Jean as part of our research team. She has been such an asset to HOG research by not only bringing with her the community perspective over the years, but served as a model for developing a very successful community research site.

“I feel that HOG was instrumental in my early education regarding the conduct of clinical trials. Now I return to assist the HOG in monitoring data quality. I consider my task to not only check quality of data, but educate community sites where needed and develop closer relationships between the community sites and the main HOG office.”

Mary Jean lives in South Bend, IN with her husband. She enjoys several hobbies including rubber stamping, making greeting cards, scrapbooking, completing unfinished needlepoint projects, and reading.

Thank you, Mary Jean, for all your dedication and hard work. You’re the best of the best!

HOG WELCOMES NEW OPERATIONS STAFF

The Hoosier Oncology Group is pleased to welcome three new members of our research operations team, **Alison Coombs**, **John Mathis** and **LeaEtta Hyer**.

We are excited to have this new talent on our team and we anticipate using their clinical perspective in streamlining some of our processes and continuing the trend of improved quality in the delivery of our services.

In their own words, each tells a little about themselves:



Alison Coombs, Regulatory Coordinator

I am very excited to be the new Regulatory & SAE Coordinator at the Hoosier Oncology Group. I come with 6 years research experience in the areas of obesity, endocrinology, neuroscience, women's health, and oncology. I grew up in Springfield, MO, and attended University of Cincinnati where I obtained a BS in dietetics. Outside of work I spend most of my time volunteering and being outside.

Contact Info: acoombs@iupui.edu; 317.634.5842 ext. 12



John Mathis, Data Manager & Project Manager

I am a new RDM here at the HOG. I grew up here in Indy and the surrounding areas but have spent time in Florida, Pennsylvania, New Jersey and even a few months in Germany. Although I had a scholarship in music, I also earned degrees in English education and nursing. I worked my way up the ranks in the pharma world as a Clinical Research Coordinator, Clinical Data Manager and Senior Technical Trainer for EDC. I have worked for Eli Lilly, Knoll Pharma, Abbott Labs and Schering Plough doing Phase I-IV

trials. Most recently, I was a nurse at the IU Simon Cancer Center. As a musician, I have been a vocal bass soloist and section leader, performed in a few operas, opened a concert for the Oak Ridge Boys and performed for (then) President Reagan. Current hobbies include playing guitar, creative writing and carpentry. I was married for 8 years and have a daughter who is a sophomore at IUPUI.

Contact Info: jjmathis@iupui.edu; 317.634.5842 ext. 13



LeaEtta Hyer, Project Manager Consultant

I come to Hoosier Oncology Group with 14 years of oncology nursing experience, 6 of it being a Research Nurse. I graduated from St Xavier University in Chicago Illinois with my BSN in 1992. I grew up about 40 miles south of Chicago, then 7 years ago relocated to the Indianapolis area. I am looking forward to the new challenge of Project Manager Consultant. My husband, Eric and I have been married for 5 years and have a 4 year old daughter,

Renee. I enjoy spending time with family as well as reading and baking.

Contact Info: lehyer@iupui.edu; 317.634.5842 ext. 26

TOP ENROLLERS IN Q2

- **IUSCC: 10**
- **NICRC: 5**
- **Siteman Cancer Center: 3**
- **Ft. Wayne Hematology/Oncology: 2**
- **Indiana Oncology/Hematology Consultants : 2**

Thank you to all our dedicated physicians and research staff for your continued support of these important trials.

OTHER HAPPENINGS

The Hoosier Oncology Group strongly promotes the support of other cancer organizations. We feel all of us must work together to ease the burden of cancer on patients and their families.

Sept. 19th — I.W.I.N. Fall mum sale. I.W.I.N organization supports women recovering from breast cancer. Order mums online Now!

Sept. 26th — Cancer Free Lungs 5K run and 1 mile stroll. Visit the website for more details.

Ovar'Coming Together dining out nights. See participating restaurants and dates.

If your site supports an organization, send us the information and we'll post it in the newsletter. Contact Deb Cole at cole22@iupui.edu.

IN MEMORANDUM

The Hoosier Oncology Group would like to acknowledge the passing of HOG family member, Dr. Juan Garcia.

Dr. Garcia was an oncologist and HOG investigator at the NICRC. We wish to share our condolences with the Garcia family.

He will be fondly remembered and missed by all.

AMENDMENT CORNER

BRE07-126 - Protocol current version date 20JUL2009; ICS v3.

GI05-102—Protocol current version date 25MAR2009. ICS was NOT amended.

GI06-101— Protocol current version date 03JUN2009; SPM current version date 13MAY2009.

GU07-122—SPM current version date 19AUG2009.

GU07-124 - Protocol, SPM and ICSv3 current version date 31JUL2009.

GYN06-111— Protocol current version date 10FEB2009. ICS v2 dated 14AUG2009.

STUDY OPENED / CLOSED

OPENED: LUN06-113 (reopened), BRE07-126; GU07-122 (reopened); GI05-102 (reopened)

CLOSED: BRE06-109; LUN06-116; LUN07-130, COE02.



Hoosier Oncology Group, Inc.

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STUDY UPDATES (past 30 days)

LUN07-130 – “Phase I Study of Amrubicin and Cyclophosphamide in Patients with Advanced Solid Organ Malignancies” second cohort re-opened; 1 slot remaining. Contact Corinne Williams at 317.634.5842 x14 prior to approaching a patient. (Effective 8/19/2009)

GI05-102 - "Phase I/Randomized Phase II Study of Second Line Therapy with Irinotecan and Cetuximab with or without RAD001, an Oral mTOR Inhibitor for Patients with Metastatic Colorectal Cancer" has 1 slot are available in Phase I Cohort 2. Contact Colleen Currie if you have a potential patient at 317.634.5842 x30. (Effective 8/19/2009)

COE02 -"Predicting Response and Toxicity in Patients Receiving Paclitaxel and Avastin for Breast Cancer: A Multicenter Genomic, Proteomic and Pharmacogenomic Correlative Study" is closed due to slow accrual. Continue protocol treatment for enrolled patients. (Effective 7/31/2009)

LUN06-116/H6Q-MC-S034 - "Randomized, Double-Blind, Phase 2 Study of Pemetrexed + Carboplatin + Bevacizumab + Enzastaurin versus Pemetrexed + Carboplatin + Bevacizumab + Placebo in Chemo-naïve Patients with Stage IIIB or IV Non-Small Cell Lung Cancer" is now terminated. No further follow up data will be collected for this trial. Notify your IRB of this termination and submit IRB acknowledgment of the termination to the Hoosier Oncology Group. (Effective 07/29/2009)

GU07-124 - "A Phase II Study of Neoadjuvant Dasatinib plus LHRH Analogue Therapy in High-Risk Localized Prostate Cancer" is open at University of Chicago (Dr. Posadas).

GU07-122 - "A Pilot Study of Neoadjuvant Dasatinib Followed by Radical Cystectomy for Transitional Cell Carcinoma of the Bladder" has passed the interim analysis and is open for accrual of 25 patients. (Effective 6/26/2009)

PROJECT MANAGERS & DATA CONTACTS

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Studies: BRE-126, COE03, GI-92, GU-75, GYN-111, LUN-77, LUN-70, LUN-99, LUN-113, LUN-129, LUN-130, LUN-137/SMO, QL-37, TBC-142

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Studies: BANK-138, BRE-120/120H

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Studies: BRE-109, BRE-120, BRE-126, COE03, GI-112, GU-75, LUN-77, LUN-99, LUN-113, LUN-116, LUN-129, LUN-130, QL-37

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Studies: BANK-138, BRE-80, BRE-140, COE01, COE02, COE05, GI-53, GI-101, GI-102, GI-103, GU-122, GU-123, GU-124, GYN-111, MDS-85